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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,635	03/24/2004	Jun Feng	DPP-IV-5004-U	8938
32793	7590	08/09/2006	EXAMINER	
TAKEDA SAN DIEGO, INC. 10410 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121			HABTE, KAHSAY	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,635	FENG ET AL.	
	Examiner	Art Unit	
	Kahsay Habte	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-111 is/are pending in the application.
- 4a) Of the above claim(s) 30-36, 40-54 and 57-111 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29, 37-39, 55 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/19/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-111 are pending in this application.

Response to Amendment

2. Applicant's amendment filed 6/19/2006 in response to the previous Office Action (12/20/2005) is acknowledged. Rejections of claims 1-5, 8-9, 11-17, 19, 23, 26-27, 29, 37-39, 51-57, 83-84, 95 and 99 under 35 U.S.C. § 112, second paragraph (items 6d-6g) have been obviated. The second paragraph rejection (items 6a-6c) has been maintained. The prior art rejection under 102(b) has been obviated by the negative proviso, but the proviso is a new matter.

Election/Restriction

3. Applicant's election of a single species: 2-[2-(3-Amino-piperidin-1-yl)-6-fluoro-4-oxo-4H-quinazolin-3-ylmethyl]-benzonitrile (Example 6 disclosed at page 115 of the specification) filed 11/30/2005 is acknowledged. Applicants traverse the restriction requirement and did not amend the claims as suggested in the previous Office Action. Applicants argue, "The present claims are drawn to a single invention and restriction, to the extent that it is applicable at all, should be based only on a restriction as to species...In this regard, claim 1 is a genus claim (i.e. generic) that links the species claims act to prevent restriction between inventions, even when the inventions would otherwise be divisible. MPEP 809.03. Accordingly, claim 1 is a linking claim that should be examined with the invention elected, and if allowable, the restriction requirement

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should be withdrawn. MPEP 809". The examiner disagrees with applicants:

Applicants have elected a species and the examiner searched the invention by expanding the variables around the elected species. The search was stopped when the examiner found a prior art. Applicants have amended the claims to overcome the prior art rejection, but the amendment necessitated a final rejection.

As it was discussed with Mr. Mitchell Brustein on 8/2/2006, the nature of the invention is very broad (see for example restriction requirement of a related case 10/809,637).

Even though not required, the examiner has again extended the search around the elected species (e.g. R_3 and R_4 form a benzo ring, and R_m = any ring, and R_2 = cycloalkyl or N-containing ring) and found another prior art.

Claims 30-36, 40-54 and 57-111 are withdrawn as not being readable on the elected species.

Information Disclosure Statement

4. Applicant's Information Disclosure Statement, filed on 6/19/2006 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-5, 8-9, 11-13, 15-17, 19, 23, 26-27, 29, 34 and 37-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The proviso "that when Q is CO, R₃ and R₄ form a benzo ring, and R₂ is 4-benzyl-1-piperidinyl, R₁ is not benzyl" lacks description. Even a negative limitation requires description, *Ex Parte Grasselli*, 231 USPQ 393.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8-9, 11-15, 17-18, 24, 26, 29, 38-39 and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Somasekhara et al. Indian Journal of Pharmacy (1972), 34(5), 121-2. Cited reference at page 122 discloses four compounds of interest: 2-cyclopropyl-3-(phenylmethyl)-4(3H)-quinazolinone; 2-cyclopropyl-3-(phenylethyl)-4(3H)-quinazolinone; 6-chloro-2-cyclopropyl-3-(phenylmethyl)-4(3H)-quinazolinone; and 6-chloro-2-cyclopropyl-3-(phenylethyl)-4(3H)-quinazolinone that are the same as applicant when applicant's Formulae X and XI have the following substituents:

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Q = CO; R₁ = benzyl or phenylethyl (i.e. Z = CH₂ or CH₂CH₂ and R_m = phenyl); R₃ and R₄ = benzo or chloro-substituted benzo; and R₂ = cyclopropyl.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-29, 37-39 and 55-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. Claim 1 and claims dependent thereon are rejected because the term "substituted" is indefinite. In the absence of the specific moieties intended to effectuate modification by the "substitution" or attachment to the chemical core claimed, the term "substituted" renders the claims in which it appears indefinite in all occurrences wherein applicants fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicants regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed.

Response to arguments

Applicant's argument filed 06/19/2006 has been fully considered but it is not persuasive.

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Applicants argue by reciting *Ex parte Lani S. Kangas*, *Mieczyslaw H. Mazurek*, *Kurt C. Melancom*, *Valter R. Romanko*, and *Audrey A. Sherman*, Appeal No. 2002-0250 (BPAI 2002). Applicants also argue by providing the definition of “substituent” from a literature and pointing out the guidance at paragraph [0098] in the specification. In regard to the appeal, every case is judged on its own merit. Since the cases are different one from the other, it is irrelevant to relate a board decision in SN 08/930,771. Note that a disclosure in SN 08/930,771 could have been self-explanatory. This is not the situation with the instant case. The specification paragraph [0098] is not limited to the examples given in said paragraph. It is also noted that some of the examples disclosed in the specification for the term “substituent” are not in fact substituents e.g. ester, ketone, aldehyde, etc. It is recommended that applicants recite specific substituents from paragraph [0098] e.g. alkyl, oxo, etc. into the claims to overcome this rejection.

b. In claim 1, the phrase “R₃ and R₄ are taken together to form...5 or 6-membered ring” is indefinite. What is the nature of the ring? What is covered and what is not? It is recommended that applicants amend the claim as “R₃ and R₄ are taken together to form...a benzo ring”.

Response to arguments

Applicant's argument filed 06/19/2006 has been fully considered but it is not persuasive.

Applicants argue by providing a dictionary that defines "ring", but this is not sufficient to overcome the rejection. The issue is not whether the term "ring" is not clear, but whether the term "ring" is indefinite or not. Applicants are silent to answer simple questions raised in previous Office Action. What is covered by ring what is not? Is a polymer compound with a ring included or not? Is it heterocyclic ring? Is it heteroaryl ring? Bicyclic ring? Tricyclic ring? Polycyclic? Aromatic ring? Fused ring? Spiro ring? Note that "ring" literally covers any compound with a cyclic nature. There is no guidance in the specification that enables one skilled in the art to understand what the term "ring" encompasses. It is recommended that applicants clearly define the term "ring" to overcome this rejection. Note that a "ring" without heteroatom, size or nature of the ring is indefinite.

c. In claim 1, the phrase "Z is a moiety providing 1-6 atom separation" is indefinite. What is covered and what is not? It is recommended that applicants amend the claim as suggested in 8.

Response to arguments

Applicant's argument filed 06/19/2006 has been fully considered but it is not persuasive.

Applicants argue, "[t]hose skilled in the art would readily understand that Z is a 'linker' that joins R_m to the ring nitrogen of the compound of Formula X." The examiner disagrees with applicants. The issue is not whether one skilled in the art knows what a

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linker mean, but what is covered by linker and what is not. It is recommend that applicants recite specific linkers as it was done in claim 8.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone

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number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Kahsay Habte', is positioned above the printed name.

Kahsay Habte
Primary Examiner
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August 7, 2006